FamiliesUSA
20 Years as the Voice for Health Care Consumers

December 23, 2002

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

www.fda.gov/dockets/ecomments

RE: **Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, Proposed Rule, Docket Number 02N-0417.**

To Whom It May Concern:

Families USA is pleased to submit these comments on the above referenced proposed rule, published in the Federal Register on October 24, 2002. Families USA is a consumer advocacy organization. For over 20-years, we have represented the interests of health care consumers nationwide.

Our interest in this proposed rule stems from our mission: the achievement of high-quality, affordable health care for all Americans. Access to affordable prescription drugs is a critical component of health care. Timely access to generics makes prescription drugs more affordable for consumers and other health care payers. Brand-name drug manufacturers' inappropriate manipulation of provisions in the Hatch-Waxman legislation has delayed the public's access to generic drugs and cost consumers and the health care system hundreds of millions of dollars.

Families USA is particularly well positioned to comment on the proposed rule. We actively monitor pharmaceutical industry practices and have joined as a plaintiff in lawsuits related to inappropriate Orange Book listings and abuse of the 30-month stay provision. We represent consumers' interests only; Families USA receives no funding from the pharmaceutical industry.

Our comments separately address each of the three areas covered by the proposed rule: the types of patents that must and must not be listed in the Orange Book; the Patent Certification Statement; and, the 30-month stay.

1334 G Street NW ◆ Washington, DC 20005 ◆ 202-628-3030 ◆ Fax 202-347-2417
E-Mail: info@familiesusa.org ◆ Web site: www.familiesusa.org

Types of Patents that Must and Must Not be Listed.

We commend the FDA for recognizing the need to clarify what patents must and must not be listed. Specifically, we support the proposal to amend the current listing regulation to clearly state that patents claiming metabolites, packaging, and intermediates are ineligible for Orange Book listing. However, we do not support the inclusion of product-by-process patents and patents claiming a different form of the approved drug substance ("polymorph" patents) among the patents that must be listed. The inclusion of these types of patents is an inappropriate expansion of the FDA's current interpretation of Hatch-Waxman's listing requirement and is open to abuse by NDA holders.

Product-By-Process Patents

We believe that product-by-process patents must not be listed, concurring with the Federal Trade Commission's (FTC) interpretation of Hatch-Waxman.[1] In its recent report on generic drug entry, the FTC stated, "the listing regulation and Hatch-Waxman's legislative history prohibit the listing of process patents, and product-by-process claims are arguably similar to process patents than are product patents….the wording of the product-by-process claim more closely resembles that of the process claim, not the product claim."[2] The proposal to include product-by-process patents among patents that must be listed is not only contrary to the legislative history of Hatch-Waxman, but will likely lead to confusion among, and abuse by, NDA holders. The potential for confusion is even noted in the preamble to the proposed rule[3] and the potential to use product-by-process patents as a device to list what are actually process patents is noted in the FTC's report.[4]

Patents Claiming a Different Form of the Approved Drug Substance (Polymorph Patents)

As noted in the preamble to the proposed rule, it has been the FDA's longstanding position that patents must claim the approved drug product or the drug product that is the subject of the application. We agree with the interpretation noted in the FTC's report that different polymorphs

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1 *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal Trade Commission (Washington, D.C., July 2002).

2 Federal Trade Commission, op. cit., page A-43.

3 The preamble to the proposed rule states: "We are concerned, however, that persons unfamiliar with patent law might confuse product by process patents with process patents, and seek to list process patents with us." (Federal Register, Vol. 67, No. 206, page 65452).

4 In its report, the FTC notes the similarities of product-by-process and product patents and illustrates how, through simple rewording, a process patent could be listed as a product-by-process patent. "A *product* patent claim would recite 'such and such substance.' A related *process* patent claim would recite 'a process for making such and such substance by performing steps (a) and (b).' A corresponding *product-by-process* patent claim would simply rearrange words of the process claim to recite 'such and such substance made by the process of performing steps (a) and (b).' " (Federal Trade Commission, op. cit., pages A-42-A-43.)

of the approved active ingredient are not part of the approved drug product.[5] As such, patents claiming different polymorphs should not be listed.

The FDA's current interpretation of Hatch-Waxman and current listing regulation appropriately exclude polymorph and product-by-process patents from those that must be listed. Given the current abuses in patent listing—many of which are outlined in the preamble to the proposed rule—expanding listable patents beyond the FDA's historic interpretation of Hatch-Waxman is inappropriate and unwise.

Patent Certification Statement

Again, we commend the FDA for recognizing that changes are needed to curb inappropriate patent listings. The Patent Certification Statement is a first step but does not go far enough. It falls short of a real review of patent listability.

Current misuse of patent listings shows that real review is necessary. However, relying on certifications from NDA holders is not enough to stop abuses. The FDA should go beyond merely requiring a statement from NDA holders and establish an administrative procedure for real review of listability, with delisting for those patents that do not meet listing requirements. Families USA believes that such a process is critical and that, without such a process, abuses that delay generic entry will continue.

The 30-Month Stay

While it is Families USA's position that no 30-month stay provision is necessary, we recognize that such a change is beyond the scope of rulemaking. Within the context of current law, we believe that limiting NDA holders to one 30-month stay per drug product per ANDA is an appropriate interpretation of the Hatch-Waxman legislation. However, we are concerned that the structure of the one 30-month stay as proposed may result in further delays in consumers' access to generics.

Currently, an ANDA applicant provides notice to the NDA holder for each unexpired patent the NDA holder lists. The NDA holder has 45-days from receipt of notice to bring a patent infringement suit against the ANDA applicant. Because a lawsuit triggers the 30-month stay provision, the NDA holder has an incentive to litigate. However, even if the NDA holder does not litigate, the ANDA applicant can bring an action for declaratory judgment. This provides resolution to patent issues by the time the

5 In its report, the FTC notes two arguments for excluding polymorph patents from listable patents: (1) patents claiming the different polymorphs do not claim the approved drug product and (2) the listing analysis is rooted in patent concepts and because brand-name companies can obtain a separate patent on a later polymorph form, the approved drug product and the polymorph are not the "same" for patent purposes. (Federal Trade Commission, op. cit., page A-41.)

generic enters the market.

The proposed rule may remove the mechanisms that currently allow ANDA applicants to have a resolution to legitimate patent disputes before going to market. The proposed rule eliminates the requirement that an ANDA applicant provide the NDA holder with notice related to patents listed after the initial Paragraph IV certification. This may also eliminate the option for an ANDA applicant to seek a declaratory judgment if the NDA holder does not initiate a lawsuit, an option currently available if the NDA holder does not bring suit within 45-days of notice. Further, since litigation will not trigger a second 30-month stay, the NDA holder will not have an incentive to file a lawsuit to provide an early resolution to the patent dispute. With no incentive for NDA holders to litigate and no option for ANDA applicants to seek resolution on legitimate patent questions, it is possible that ANDA applicants may face an open-ended threat of legal action related patents listed after the initial Paragraph IV certification. Facing such a threat, ANDA applicants may be hesitant to bring generics to market.

Giving ANDA applicants the option to certify patents listed after the initial Paragraph IV certification and to seek declaratory judgment if the NDA holder does not bring suit within a specified time period would resolve this issue, although that resolution may be beyond the scope of rulemaking.

Conclusion

Although we are pleased that the FDA recognizes the need to address NDA holders' inappropriate manipulation of current laws, as outlined in our comments, we are concerned that the proposed rule will not result in greater access to generics. While the proposed rule provides needed clarification on the types of patents that can be listed in the Orange Book, including product-by-process and polymorph patents among listable patents is inappropriate and could result in continued abuses. The proposed Patent Certification Statement is a good first step, but it is insufficient to provide the real review of listability necessary to curb abuses. While we strongly support the proposed limitation in the 30-month stay provision in principle, we are concerned that, as structured, it may create uncertainty for ANDA applicants that could result in even greater delays in generic marketing.

Although the proposed rule can be improved so that it better meets the goal of ensuring appropriate access to generics, rulemaking alone cannot correct existing abuses. Legislation is necessary. Current law needs to be corrected to either remove the 30-month stay or to ensure that the limitation of one 30-month stay is not challenged in court. While we believe that this authority does exist in current law, explicit statutory changes would ensure that this interpretation is followed by the courts. Limitations on the 30-month stay need to be made in conjunction with a requirement that NDA holders promptly list patents, and with provisions for substantive review of listability and a mechanism for ANDA applicants to challenge Orange Book listings.

Medications are an important part of comprehensive medical care and millions of Americans are without prescription drug insurance. Appropriate, timely access to lower-cost generic drugs will make medicines

more affordable for millions of consumers and will help to reduce health care costs for other payers as well.

The FDA's recognition of the need to correct inappropriate manipulation of current law is an important first step; however, it falls short of what is necessary and some of the proposed changes may even increase barriers to generic entry.

We appreciate the opportunity to submit these comments.

Sincerely,

Ron Pollack
Executive Director